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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndl	0050/49860	8414

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/937,313	BERNDL ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12,14-18 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12,14-18 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 2/1/08

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12, 14-18, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Guzi Jr. et al (USPN 4,127,422 hereafter '422) in view of Staniforth et al (USPN 5,858,412 hereafter '412) or Zeligs et al (USPN 6,086,915 hereafter '915).

The claims are drawn to a process fro making an excipient comprising spray drying a composition comprising 10-50% of a surfactant and a vinylpyrrolidone polymer.

The '422 patent teaches a method of making an excipient comprising spray-drying a solution comprising 15-40 % by weight of a nonionic dispersing agent, and a polymer such as N-vinylpyrrolidone (col. 2, lin. 20-60). The nonionic dispersing agents have an HLB greater that 11, specifically from 12-18 (col. 3, lin. 5-10). The N-vinylpyrrolidone has a K-value from 15-21 (example 9). The excipient comprises a pigment (examples). The formulation is also processed with a concentration of water that is removed during processing to result in a dry powder material (claims). After spray drying the powders are ground through a 1/16-inch (12-mesh

screen (examples). This would indicate that particles were roughly as large as 1586 microns are present in the final product. However since smaller particles must also be present in order to have fit through the mesh screen. It is the position of the Examiner that some if not most of the particles would be with within the range of the instant claims. It would be obvious to one of ordinary skill in the art to found particles ranging from 10 microns to 1 mm in the resulting free flowing excipient given the spraying and grinding techniques disclosed in the reference and known in the art.

Regarding the drop point of claim 11, although the reference is silent to a specific drop point, the reference teaches surface-active compounds that are similarly identified in Applicant's specification. As such all of the inherent properties such as drop point are encompassed by the surfactants of the '422 patent. The instant specification identifies polyoxyethylene ethers and fatty acids as useful in the invention. These are all disclosed by the prior art. It is the position of the Examiner that these polymers would inherently meet the limitations of the claims.

The surfactants can be selected from the group consisting of ethoxylated fatty acid esters and polyoxyethylene fatty glycerides (col. 3, lin. 30-40). The reference does not disclose the specific surfactant so of claims 15 or 16 yet suggest similar polymers in similar concentrations. The inclusion of these surfactants into microparticulate formulations is well known in the art as can be seen in the '412 and '915 patents.

The '412 patent discloses microparticulate formulation comprising various surfactants including polysorbate 40, an ethoxylated sorbitan fatty acid ester (col. 11, lin. 25-30), in a concentration up to 20% (col. 13, lin. 47-52, claim 24). The particles are spray dried (col. 14, lin. 35-39). The resulting particles measure from 10-500 microns (col. 14, lin. 58-64). The

formulation further comprises up to 50% adjuvants such as polyvinylpyrrolidone (col. 18, lin. 53-58). It would have been obvious to include the surfactants of the '415 patent in order to improve the compressibility of the resulting microparticles.

The '412 patent also suggests the inclusion of castor oil derivatives as possible surfactants (col. 11, lin. 34). The inclusion of specific castor oil derivative are well known in the art as seen in the '915 patent. The '915 patent disclose a microparticle carrier formulation comprising 10-40% polyvinylpyrrolidone and 5-20%, an ethoxylated castor oil (col. 12, lin. 35; col. 16, lin. 17-27). The skilled artisan would have been motivated to include the surfactants of the '415 patent in order to improve the stability of the spray dried particles as well.

One of ordinary skill in the art would have been motivated to combine the surfactants of the '415 and '915 patents in order to provide improved stability and compressibility of the microparticles resulting from the spray drying. It would have been obvious to combine these components in order to provide an improved method of making a carrier composition with improved stability.

Claims 10, 15, 16, 18, 20 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Kolter et al (USPN 6,066,334 hereafter '334) in view of Staniforth et al (USPN 5,858,412 hereafter '412) or Zeligs et al (USPN 6,086,915 hereafter '915). The claims are drawn to a method of making an excipient comprising 10-50 % of a surfactant and a polymer of polyvinylpyrrolidone, wherein the formulation does not comprise a pigment.

The '334 patent discloses a redispersible microparticle formulation comprising polyvinylpyrrolidone and up to 10% of a surfactant including both ionic and nonionic surfactants

(abstract; col. 3, lin. 32-35). The polyvinylpyrrolidone has K-values from 30-50 (col. 3, lin. 4-12). The resultant particles have an average size of 1000 microns and are spray-dried (example 1). The formulation further includes binders, lubricants and further bulking agents (col. 4, lin. 51-65), yet is free of pigments.

Although the reference indicates that the emulsifiers are present in a concentration up to 10%, they are not exemplified to this range. However the wide range of the concentration would be within the level of ordinary skill of an artisan to optimize in order to arrive at the presently claimed invention. The general conditions of the claims have been met, specifically a process for making an excipient comprising spray drying a composition comprising polyvinylpyrrolidone having K-values from 30-50, and at least 10% of a surfactant. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the specific surfactant/emulsifiers, it is the position of the Examiner that it would have been well within the level of skill in the art to simply substitute the

emulsifiers/dispersing agents of the '412 and '915 patent into the '334 patent. The '34 patent discloses that both ionic and nonionic surfactants are useful in the invention.

The '412 patent discloses microparticulate formulation comprising various surfactants including polysorbate 40, an ethoxylated sorbitan fatty acid ester (col. 11, lin. 25-30), in a concentration up to 20% (col. 13, lin. 47-52, claim 24). The particles are spray-dried (col. 14, lin. 35-39). The resulting particles measure from 10-500 microns (col. 14, lin. 58-64). The formulation further comprises up to 50% adjuvants such as polyvinylpyrrolidone (col. 18, lin. 53-58). It would have been obvious to include the surfactants of the '415 patent in order to improve the compressibility of the resulting microparticles.

The '412 patent also suggests the inclusion of castor oil derivatives as possible surfactants (col. 11, lin. 34). The inclusion of specific castor oil derivative are well known in the art as seen in the '915 patent. The '915 patent disclose a microparticle carrier formulation comprising 10-40% polyvinylpyrrolidone and 5-20%, an ethoxylated castor oil (col. 12, lin. 35; col. 16, lin. 17-27). The skilled artisan would have been motivated to include the surfactants of the '412 patent in order to improve the stability of the spray dried particles as well.

One of ordinary skill in the art would have been motivated to combine the surfactants of the '412 and '915 patents in order to provide improved stability and compressibility of the microparticles resulting from the spray drying. It would have been obvious to combine these components in order to provide an improved method of making a carrier composition with improved stability.

Response to Arguments

Applicant's arguments filed 2/01/08 have been fully considered but they are not persuasive. Applicant argues that:

> The ‘422 patent in combination with the '412 and '915 patents do not obviate the claims since the ‘422 des not disclose the method of the instant claims and the ‘421 and ‘915 patents do not solve the deficiencies.

Regarding this argument it remains the position of the Examiner that the combination continues to obviate the instant claims. Applicant argues that since the '422 patent can be used as a pigment in paints or textile product, the patent invention cannot be used in pharmaceutical dosage forms. However the claims recite that the excipient is adapted for use in a pharmaceutical. The '422 patent does create a pigment excipient; however this does not remove the possibility of the formed pigment being used in pharmaceutical dosage forms as a pigment. The current claims indicate that the excipient must merely be adapted for use, meaning that it can be present in one form but merely be capable of other used not initially intended. Pigments are commonly used in pharmaceutical dosage form s to distinguish dosage forms from another and for aesthetic purposes or for shielding the active agents from photo-degradation. It remains the position of the Examiner that the pigments created by the '422 patent would be useful in pharmaceutical dosage forms for a variety of reasons. Further the '422 patent meets the process limitations of the instant claims. The claims recite that an excipient is created by spray drying a composition comprising a copolymer of vinylpyrrolidone with specific K-values, and 10-50% of a surfactant such as ethoxylated sorbitan fatty acid or products of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid. The '422 patent discloses a method of forming an excipient comprising spray drying a formulation comprising a copolymer of

vinylpyrrolidone and 15-45% of a surfactant where the surfactant includes ethoxylated fatty acid. This is suggestive of the specific surfactants recited in claims 15 ad 16 and the surfactants discloses in the '412 and '915 patent. Each patent discloses surfactants that are similar to those disclosed in the '422 patent and would have been obvious to substitute since all of the surfactants are well known in the art. It would be obvious to substitute well known compounds into a well known processing method in order to make a common product. For these reasons the claims remain rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618